

EMERGENCY REGULATION
DEPARTMENT OF PESTICIDE REGULATION

TITLE 3. FOOD AND AGRICULTURE
Data Cost-Sharing

FINDING OF EMERGENCY

The Department of Pesticide Regulation (DPR) finds that pursuant to section 12811.5(d) of the Food and Agricultural Code (FAC), an emergency exists and that the adoption of these regulations is necessary for the immediate preservation of the public peace, health and safety, or general welfare.

INFORMATIVE DIGEST

Existing law requires every manufacturer, importer, or dealer of any pesticide to obtain a certificate of registration from DPR before the pesticide is offered for sale. In support of the registration, an applicant for registration must submit human health and environmental fate data.

Until January 1, 2006, FAC section 12811.5 provided that if an applicant did not submit its own data to fulfill DPR's data requirements for a new pesticide product or an amendment to a currently registered pesticide product, and the applicant wished to rely upon data owned by another company, DPR needed written authorization (letter of authorization) from the appropriate data owner. If an applicant did not wish to, or could not, obtain a letter of authorization from a current data owner, then the applicant had to submit its own duplicate data to DPR.

Assembly Bill 1011 (Chapter 612, Statutes of 2005) changed state law regarding how DPR treats data submitted in support of product registration. FAC section 12811.5 now allows DPR to consider evaluations of all data it has on file, regardless of the source of the data. The new law did not change any of DPR's data requirements, and applicants may still submit their own data in support of a registration application. However, if an applicant does not do so, and instead relies on another company's data to support its registration application, the applicant may be required to make an offer to pay the data owner.

FAC section 12811.5(d) requires DPR to adopt emergency regulations to establish a proceeding to resolve disputes over the terms and amount of payment required under this new law if agreement cannot be reached at any time more than 90 days after issuance of an irrevocable offer to pay. The proposed regulations provide that either the applicant, source, or data owner may initiate or, with the consent of all parties, join a binding dispute resolution proceeding under the rules prescribed under Title 29 Code of Federal Regulations, Part 1440; or its successor provision, if any; or other rules to which the applicant and data owner may agree.

SPECIFIC FACTS SHOWING NEED FOR IMMEDIATE ACTION

FAC section 12811.5 allows DPR to rely upon any evaluations of previously submitted data with respect to an application for registration, an amendment to a registration, or to maintain a registration. DPR is not required to monitor or police data ownership when making registration decisions. The law specifically states that, when making registration decisions, DPR can rely on evaluations of any data on file, regardless of data ownership.

FAC section 12811.5 states that if the applicant or the source of the applicant's product is required to make an offer to pay a data owner, this offer must be made by the date an application is submitted to DPR. The specific terms and amount of payment shall be fixed by agreement between the applicant and the owner, but shall not delay approval of the applicant's application. However, if the applicant and the data owner cannot agree on the amount and terms of compensation within 90 days of the offer, either party may initiate a proceeding under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), pursuant to emergency regulations adopted by DPR to resolve disputes concerning compensation.

FAC section 12811.5(d) requires the Director to promulgate emergency regulations to prescribe in more detail the proceeding authorized by the statute to resolve disputes over the terms and amount of cost-sharing required by FAC section 12811.5. DPR proposes to adopt Article 15, Data Cost-Sharing, in Title 3, California Code of Regulations (3 CCR) to provide this detail on the proceeding and subsequent results as follows:

- Proposed 3 CCR section 6310 would allow the proceeding to be combined with any dispute resolution process taking place between the same parties and conducted under FIFRA; require the decisionmaker to consider that the data owner recovered all or part of its costs of generating data by having an exclusive right to sell the pesticide for some period of time; specify that the finding of the decisionmaker shall be final and conclusive; and that the parties to the dispute resolution proceedings equally share in the payment of fees and expenses.
- Under 3 CCR, Article 2, Registration Requirements, section 6170, proposed changes have been made to be consistent with the changes to FAC section 12811.5.

AUTHORITY

This regulatory action is being taken pursuant to authority vested by FAC sections 12781 and 12811.5.

REFERENCE

This regulatory action implements, interprets, or makes specific FAC sections 12811, 12812, 12815, 12816, and 12811.5.

MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DPR has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a new program or higher level of service of an existing program within the meaning of section 6 of Article XIII B of the California Constitution. DPR has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

DPR has determined that no savings or increased costs to any state agency will result from this regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

DPR has determined that no effect on federal funding to the state will result from this regulatory action.